

REMARKS

Claims 1 and dependent claim 3 were rejected as anticipated by Davidson and dependent claim 2 was rejected as obvious over Buechel et al. in view of Davidson. These grounds of rejection are submitted to be inapplicable to the claims as amended for the reasons which follow. In addition, claims 4-11, 17 and 19 were rejected for multiple dependency, now corrected by the foregoing amendment. Reconsideration and examination of the amended claims is requested.

Claim 1 has been amended to add the limitation that the metal-containing layer is applied not merely by a vacuum coating process but specifically by means of "electron beam vaporization under a pressure from 10^{-4} to 10^{-2} mbar." Neither of the above-mentioned references relied on for rejection contains a single reference to electron beam vaporization, let alone the pressure range now recited in claim 1.

Davidson discloses the possibility of applying zirconium coatings by vapor deposition. However, the preferred process in Davidson is in-situ oxidation or nitridation of zirconium (see, e.g., column 3, lines 19-20). Davidson could not be more explicit in repeatedly emphasizing that dense coatings are thereby created. "[T]he thickness of the coating is not critical other than that it should be *dense*" (Davidson, column 6, lines 13-15, emphasis supplied). See also column 7, lines 8 and 13 and column 9, line 10 of Davidson. In contrast, the coating obtained by the applicants' specific electron beam vaporization system as defined in amended claim 1 is not dense, but is porous with many voids or empty spaces, owing particularly to the fact that the process is conducted at a relatively high pressure range of 10^{-4} to 10^{-2} mbar. Davidson implies dense coatings are critical; applicants recited coatings would not even qualify under this standard. So, the metalization process and the result are both different.

The defined pressure range 10^{-4} to 10^{-2} mbar is higher than the pressure commonly used in electron beam vaporization processes. See the attached pages of Instruction Manual 0101-8021-0 Temescal Electron Beam Source, December 1989, Fig. 1, pp. 2-4 and 9. On page 9 the manual directs that the chamber first be evacuated down to a pressure of 1×10^{-4} torr, i.e., 1.33×10^{-4} mbar *or less*. As this is only the starting pressure, during subsequent operation, i.e., while metalization is taking place, the pressure would obviously be still lower. Further, since in

practice there are always variations in the pressure, for safety reasons, a starting pressure lower than 1×10^{-4} torr is usually sought. Thus, the pressure applied according to the invention is higher than the pressure commonly used for electron beam vaporization. More to the point, the range of 10^{-4} to 10^{-2} mbar for electron beam to make the claimed coated article is nonobvious from anything in Davidson even if one were to read (albeit impermissibly) into Davidson the possibility of using conventional electron beam vaporization.

This relatively high pressure electron beam vaporization coating technique results in porous coatings with dangling bonds on the surface of the coating enhancing the biocompatibility of the coated article. In contrast to the claimed invention, Davidson provides no teaching concerning the use of electron beam vaporization, far less the specific pressure range recited in claim 1 to provide a coating of enhanced biocompatibility. Thus amended claim 1 is not only unanticipated by Davidson, but is nonobvious from the teachings of Davidson.

The other cited reference Buechel et al. contains no reference to vapor deposition at all, let alone electron beam vaporization at the recited higher than normal pressure range. Instead, Buechel uses ion bombardment preferably to deposit titanium nitride, which is a different technology. See, e.g., column 5, line 58 and column 8, line 2 and 59 of Buechel et al. Davidson on the other hand is highly specific to the use of zirconium. Indeed, in a divisional of the cited patent, U.S. patent No. 5,632,779, Davidson denigrates titanium, stating, "In contrast, oxidation of titanium alloys tends to form multiple oxides of titanium, which are less well attached to the metal substrate." (Column 4, lines 52-54). Thus the person of average skill in this art would not consider the teachings of Buehler et al. with regard to the titanium-containing coatings compatible or even consistent with those of Davidson. Thus applicants submit that the cited Davidson and Buehler et al. references are therefore not properly combinable.

Claims 17 and 19 have been reformatted to recite a step to comply with the interpretation of section 101 advanced in the Office action, as well as to remove multiple dependency. Claim 18 has been deleted.

Because claim 1 is neither anticipated nor obvious from the cited references, taken singly or in combination, and is otherwise patentable, its dependent claims are similarly patentable over the cited references, because the dependent claims by definition include each and every

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Serial No. : 09/521,086
Filed : March 7, 2000
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limitation of claim 1. Claims 2, 3, 5-11, 17 and 19 are all dependent from claim 1. Accordingly, they are also patentable over the cited references.

Attached is a marked-up version of the changes being made by the current amendment.


Applicants request consideration by the Examiner of the information disclosure statement filed June 8, 2001 and an initialed copy of the PTO Form 1449 which accompanied the statement.

Applicants ask that all claims be allowed. Enclosed is a check for \$460 for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

December 20, 2001



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Version with markings to show changes made

In the claims:

Claims 4 and 18 have been cancelled.

Claims 1, 5, 6, 7, 9, 10, 11, 17 and 19 have been amended as follows:

1. An article comprising a substrate which is coated at least partly with at least one layer, and on which there is at least partly a protein-, peptide-and/or saccharide-containing substance, where the layer directly adjacent to the substance comprises at least one metal selected from titanium, zirconium and hafnium, or a compound thereof with one or more nonmetals and/or semiconductors, or an alloy thereof with one or more other metals, and has been applied by means of electron beam vaporization under a pressure from 10^{-4} to 10^{-2} mbar.

5. An article as claimed in [any of the preceding] claim[s] 1, wherein the thickness of the layer is between 9 and 5 μm .

6. An article as claimed in [any of the preceding] claim[s] 1, wherein the specific resistance of the layer is between 10 and 10 $\mu\Omega\text{cm}$.

7. An article as claimed in [any of the preceding] claim[s] 1, wherein the layer which is directly adjacent to the substance and has been applied by [the vacuum locating process] electron beam vaporization has undergone an aging in air.

9. An article as claimed in [any of the preceding] claim[s] 1, wherein the substance comprises at least albumin.

10. An article as claimed in [any of the preceding] claim[s] 1, wherein the substrate consists of stainless steel, tantalum, Nitinol, titanium, gold, and/or polymer.

11. An article as claimed in [any of the preceding] claim[s] 1, which is designed as a stent.

17. [The use of an article as claimed in any of claims 1 to 11 for implantation, insertion or attachment in or on the animal or human body or for] A method of using an article as claimed in claim 1, comprising the step of bringing said article into contact with human or animal blood or tissue or human or animal cells.

19. The [use] method as claimed in claim 17, wherein a substance as [defined] claimed in claim 8 [or 9] is used.